REMARKS

Claims 1-3 and 5-19 are pending in this application, with claims 1 in part, 3, 7-16 and 18-21 withdrawn from consideration. Claims 2, 3, 5-16 and 18-21 are canceled without prejudice or disclaimer, and claims 1 and 17 are amended herein. Upon entry of this amendment, claims 1 and 17 will be pending. The specification is also amended. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

The specification is objected to because of informalities. (Office action paragraph no. 4)

The Examiner states that the first paragraph in the specification should include the priority information to match the Bib Data sheet.

Applicant has amended the specification to state the 35 U.S.C. 119 foreign priority information. However, Applicant respectfully submits that it is not necessary to state this in the specification. Applicant notes that the specification has not been amended to state the status of this application as a national stage application under 35 U.S.C. 371. In a national stage application under 35 U.S.C. 371, "it is not necessary for the applicant to amend the first sentence of the specification to reference the international application number ...." (MPEP 1893.03(d)).

Claim 1 is objected to because non-elected subject matter is not cancelled from the elected claim 1. (Office action paragraph no. 7)

The objection is overcome by the amendment to claim 1, limiting claim 1 to the protein having the amino acid sequence shown as SEQ ID NO: 1.

Claims 2 and 17 are objected to because the proper way to express the homology is "a protein having at least 90% homology with said amino acid" for example. (Office action paragraph no. 7)

The rejection of claim 2 is moot in view of the cancellation of claim 2 without prejudice or disclaimer. The rejection is overcome for claim 17 by the deletion of the portion of the claim with the "90% or more homology" recitation.

Claims 1, 2, 5, 6, and 17 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. (Office action paragraph no. 8)

The Examiner states that claims 1, 2, 5, 6 and 17 are drawn to a product of nature, and suggests the insertion of "isolated" or "purified" in connection with the protein to identify a product not found in nature.

The rejection is moot for claims 2, 5 and 6, which have been canceled without prejudice or disclaimer. The rejection of claims 1 and 17 is overcome by the amendments to these claims to recite "An isolated marker protein ...," as suggested by the Examiner.

Claims 1, 2, 5, 6, and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action paragraph no. 9)

The rejection is moot for claims 2, 5 and 6, which have been canceled without prejudice or disclaimer, and is overcome by the amendment to claims 1 and 17.

The Examiner states that it is not clear how the molecular weight in the claim was determined, since the amino acid sequence is not in the claim. The molecular weight recitations in claim 1 have been deleted.

Claims 1, 2, 5, 6, and 17 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Office action paragraph no. 10)

This rejection is moot for claims 2, 5 and 6, which have been canceled without prejudice or disclaimer, and are overcome by the amendments to claims 1 and 17.

The Examiner states that no specific function is presented in reference to SEQ ID NO: 1 or its variants or a protein that has 5.9 kDa. The Examiner also states that the specification does not demonstrate possession of the different variants of the proteins, since "several deletions, additions, substitutions, can be made to the variants at issue."

In the amendments, the recitations of the proteins other than that having the sequence shown as SEQ ID NO: 1 have been deleted.

Claims 1, 2, 5, 6, and 17 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the protein having molecular weight of 5.9 kDa or SEQ ID NO: 1 (as elected), does not reasonably provide enablement for any variants of these proteins where several additions or substitutions or deletions are provided in the sequence as disclosed. (Office action paragraph no. 11)

This rejection is moot for claims 2, 5 and 6, which have been canceled without prejudice or disclaimer, and are overcome by the amendments to claims 1 and 17.

The Examiner states that there is no enablement for the variants of the proteins. The recitations of the variants of the proteins have been deleted in claims 1 and 17.

Claims 1, 2, 5, 6, and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by Garner et al. (U.S. Patent No. 5,639,940). (Office action paragraph no. 12)

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. Claims 2, 5 and 6 have been canceled without prejudice or disclaimer, and claims 1 and 17 have been limited to the isolated protein having the amino acid sequence shown in SEQ ID NO: 1.

Garner et al. (U.S. Patent No. 5,639,940) describes an amino acid sequence that includes the amino acid sequence of SEQ ID NO:1 of the present invention. However, Garner et al. does not describe the **isolated**, discrete protein of the amino acid sequence of SEQ ID NO:1, as recited in claims 1 and 17.

Furthermore, Garner et al. does not suggest the discrete and isolated protein as claimed, and certainly does not suggest that the discrete and isolated protein can be effectively a marker for diagnosing liver disease. The data in Tables 1 to 3 of Example 6 of the present specification clearly demonstrate that the patients with alcoholic liver trouble were able to be effectively diagnosed on the basis of the protein of the amino acid sequence of SEQ ID NO:1 according to the present invention (i.e., FDP-E 5.9 kDa AU).

On the other hand, Garner et al. describes no more than the production of fibrinogen in transgenic animals using the amino acid sequence that includes the amino acid sequence of SEQ ID NO:1 of the present invention.

Claims 1 and 17, as amended, are therefore not anticipated by, and not obvious over, Garner et al.

Reconsideration of the rejections and objections is respectfully requested.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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